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DAVID TOREN, ESQ.
SIDLEY, AUSTIN, BROWN & WOOD, LLP
787 SEVENTH AVENUE
NEW YORK, NY 10019-6018

EXAMINER

QUAN, ELIZABETH S

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/867,087

Applicant(s)

GULZOW ET AL.

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 31-58 is/are pending in the application.
- 4a) Of the above claim(s) 43-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 31-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of claims 1-3 and 31-42 in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "6" has been used to designate both expansion and holes. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. The drawings are objected to because reference characters "17" and "27" are directed to the same element in FIG. 6 when the specification designates "17" as the recesses and "27" as the projections. In FIG. 3 it appears the reference character pointing to the cup-shaped bottom of the vessel is a "g" when it should be a "9". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: On page 12, second paragraph of DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS "Figs. I through 3" should be "Figs 1 through 3." The specification refers to the microtitration plate as both "I" and "1", frame as both "F" and "2", and vessel as both "3" and "6". The specification refers to reference character "6" as "holes", "expansion", and "vessels". It is confusing to

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designate "I" and "1" as the microtitration plate and "7" as the plate. On page 5, third line of the last paragraph, "tit" should be "fit." On page 13, 4th line of the second to the last paragraph, "has" between "conicity as" and "the wall portion" should be deleted. On page 16, third to the last paragraph, "has" after "same as" should be deleted. On page 16, first line of the second to the last paragraph, the left quotation mark should be deleted.

Appropriate correction is required.

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unknown what non-positive and/or positive and/or material fit are. The specification simply mention these terms and do not describe what they are. Claim 3 is rejected based on its dependency on claim 2.

7. Claims 35 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and/or use the invention. It is unknown what molding points and edge-sided molding points are. The specification simply mention these terms and do not describe what they are.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 1-3 and 31-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1 recites the limitation "the underside" in line 7. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 1 recites the limitation "the upper surface" in line 8. There is insufficient antecedent basis for this limitation in the claim.

12. Referring to claim 2, it is unclear what non-positive and/or positive and/or material fit means. The specification does not provide such a description.

13. Referring to claim 35 and 37, it is unclear what are molding points and edge-sided molding points. The specification does not provide such a description.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

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patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1-3, 31-41 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,340,589 to Turner et al.

Referring to claims 1, 36, 38-41, Turner et al. disclose a microtitration plate (10) comprising a frame (11) and multiplicity of vessels (14) (see FIG. 1). The frame (11) is made of a stiff plastic from the amorphous polymer family, such as glass filled polycarbonate (see COL. 9, lines 41-67; COL. 10, lines 1-15; COL. 11, lines 32-62). The frame has a plate with a multiplicity of holes (13) (see FIG. 1; COL. 8, lines 54-67; COL. 9, lines 1-40). The frame (11) has a bordering (17a, 17b, 17c, 17d) protruding from the underside of the frame (11) at the edge of the plate (see FIGS. 1, 2a, 2b, 2c, 4, and 5). The multiplicity of vessels (14) is made of a relatively soft plastic suitable for PCR and exhibiting permeability to oxygen, such as polypropylene (see COL. 10, lines 26-67; COL. 11, lines 1-31). The multiplicity of vessels (14) are fixedly connected to the plate such that a portion of the vessels (14) protrude from the underside (see FIGS. 1, 4, and 5; COL. 4, lines 60-62; COL. 6, lines 28-67; COL. 7, lines 1-45; COL. 8, lines 43-53; COL. 12, lines 23-67; COL. 13, lines 1-67; COL. 14, lines 1-27). The limitation of directly molding the multiplicity of vessels (14) to the holes (13) has been construed as a process claim limitation (MPEP 2113). Patentability is based on the product and does not depend on its method of production. If the product is the same or obvious over a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In this case it would not matter whether or not the microtitration plate

is molded since the claimed microtitration plate is the same as the microtitration plate of Turner et al. It is noted, however, that Turner et al. disclose that the multiplicity of vessels (14) are fixedly connected to the plate by molding them to the holes (13) of the plate (see COL. 4, lines 60-62; COL. 6, lines 28-67; COL. 7, lines 1-45; COL. 8, lines 43-53; COL. 12, lines 23-67; COL. 13, lines 1-67; COL. 14, lines 1-27). The multiplicity of vessels (14) are accessible from the upper surface (15) of the plate through apertures (32) (see FIG. 1, 4, and 5).

Referring to claims 2 and 3, the vessels (14) are connected to the plate at least one portion of the sides of the vessel (14) and plate. Examiner has interpreted non-positive fit as molding the vessels and attaching them to the holes in a non-exacting manner, such that the variations in the vessels and holes contribute to a non-exacting fit. Examiner has interpreted positive fit as molding the frame and vessels in one step or molding the vessels directly on the holes or using a single mold for the vessels and frame, such that the vessels exactly fit over the holes. Examiner has interpreted material fit as even though there are variations in the vessels and holes contributing to a non-exacting fit, a supplementary structure or operation, such as a sealing structure or heat fusion between the vessels and holes makes the vessels fit better within respective holes. It is noted that the claim provides three options of fit that encompasses all imaginable fits, and certainly the method of construction provided by Turner et al. covers at least one of these three types of fits. Turner et al. disclose the molding of vessels of inherently variable cross-section in an axial direction over the respective holes of inherently variable cross-section in an axial direction for a non-positive fit (see COL. 4, lines 60-62; COL. 6, lines 28-67;

COL. 7, lines 1-45; COL. 8, lines 43-53; COL. 12, lines 23-67; COL. 13, lines 1-67; COL. 14, lines 1-27). Turner et al. also disclose the technique of using a single mold for a positive fit (see COL. 4, lines 60-62; COL. 6, lines 28-67; COL. 7, lines 1-45; COL. 8, lines 43-53; COL. 12, lines 23-67; COL. 13, lines 1-67; COL. 14, lines 1-27). Turner et al. also disclose the technique of welding or joining by adhesive between the imperfect vessels and imperfect holes for material fit.

Referring to claims 31-34, the vessels (14) have a wall portion (14a) of a thin wall thickness of about 0.15 mm to about 0.25 mm (see FIGS. 1, 3b, 3c, 4, and 5; COL. 11, lines 5-55; COL. 12, lines 1-22). Examiner has interpreted that the claim is reciting that the wall with a very small thickness is adjacent to the vessel bottom. In this case wall portion (14a) is adjacent to the vessel bottom (14b) (see FIGS. 1, 3b, 3c, 4, and 5; COL. 11, lines 5-18). Examiner has interpreted that the claim is reciting that the vessels have an upper wall portion connected to the plate. In this case the vessels (14) have an upper wall portion (34) of increased wall thickness relative to wall portion (14a) that is connected to the plate (see FIGS. 1, 3b, 3c, 4, and 5; COL. 10, lines 53-67; COL. 11, lines 5-19). The upper wall portion (34) may be characterized as a collar (see FIGS. 1, 3b, 3c, 4, and 5). The vessels (14) have a substantially cup-shaped bottom (14b) and thin wall portions (14a) that tapers to form a cone shape (see FIGS. 1, 3b, 3c, 4, and 5). Examiner has interpreted "and/or, in a wall portion (11) adjoining it, are a wall thickness which gradually increases upwardly" as the wall portion with a wall thickness which increases upwardly adjoins the thin, tapering wall portion. In this case the vessels (14)

have a wall portion (34) of a wall thickness gradually increasing upwardly adjoining the thin wall portion (14a) (see FIGS. 1, 3b, 3c, 4, and 5).

Referring to claims 35 and 37, Examiner has interpreted molding points as points that are molded. Examiner has interpreted edge-sided molding points as points at the edges and sides that are molded. Turner et al. disclose that the entire microtitration plate may be molded, including the vessel bottoms and frame and its sides and edges. Inherently, the vessel bottoms and the sides and edges of the frames have infinite molding points.

Therefore, Turner et al. include all the limitations in claims 1-3 and 31-41.

16. Claims 1-3, 31-37, 40, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,475,610 to Atwood et al.

Referring to claims 1, 36, 40, and 41, Atwood et al. disclose a microtitration plate comprising a frame (342) and multiplicity of vessels (376) (see FIGS. 21A and 21B). The frame (342) is made of a relatively stiff plastic (see COL. 38, lines 28-35). It is noted that everything has a degree of stiffness. The frame (342) has a plate with a multiplicity of holes (see FIGS. 21A and 21B). The frame (342) has a bordering protruding from the underside of the frame (342) at the edge of the plate (see FIGS. 21A and 21B). The multiplicity of vessels (376) is made of a relatively soft plastic suitable for PCR and exhibiting permeability to oxygen, such as polypropylene (see COL. 40, lines 10-18). The multiplicity of vessels (376) are fixedly connected to the plate such that a portion of the vessels (376) protrude from the underside (see FIGS. 21A and 21B; COL. 39, lines 3-59; COL. 40, lines 34-67; COL. 41, lines 1-20). The limitation of directly

molding the multiplicity of vessels (376) to the holes has been construed as process limitation (see MPEP 2113). Patentability is based on the product and does not depend on its method of production. If the product in the product-by-process claim is the same or obvious over a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In this case it would not matter whether or not the microtitration plate is molded since the claimed microtitration plate is the same as the microtitration plate of Atwood et al.

Referring to claims 2 and 3, the vessels (376) are connected to the plate at least one portion of the sides of the vessel (376) and plate. Examiner has interpreted non-positive fit as molding the vessels and attaching them to the holes in a non-exacting manner, such that the variations in the vessels and holes contribute to a non-exacting fit. Examiner has interpreted positive fit as molding the frame and vessels in one step or molding the vessels directly on the holes or using a single mold for the vessels and frame, such that the vessels exactly fit over the holes. Examiner has interpreted material fit as even though there are variations in the vessels and holes contributing to a non-exacting fit, a supplementary structure or operation, such as a sealing structure or heat fusion between the vessels and holes makes the vessels fit better within respective holes. It is noted that the claim provides three options of fit that encompasses all imaginable fits, and certainly the method of construction provided by Atwood et al. covers at least one of these three types of fits. Atwood et al. disclose the importance of a good fit between the vessels (376) and holes for good thermal conductance (see COL. 39, lines 3-59).

Applicant is reminded that the limitation of non-positive and/or positive and/or material

fit is a process limitation (see MPEP 2113). Patentability is based on the product and does not depend on its method of production. Process limitations are of no patentable moment in a claim to the product. If the product is the same or obvious over a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In this case it would not matter whether or not the vessels and holes are a non-positive and/or positive and/or material fit since the claimed microtitration plate is the same as the microtitration plate of Atwood et al.

Referring to claims 31-34, the vessels (376) have a wall portion (368) of a thin wall thickness of about 0.009 +/- 0.001 inches or about 0.20 mm to about 0.25 mm (see FIGS. 15, 21A, and 21B; COL. 40, lines 4-6). Examiner has interpreted that the claim is reciting that the wall with a very small thickness is adjacent to the vessel bottom. In this case wall portion (368) is adjacent to the vessel bottom (see FIGS. 15, 21A, and 21B). Examiner has interpreted that the claim is reciting that the vessels have an upper wall portion connected to the plate. In this case the vessels (376) have an upper wall portion (384) of increased wall thickness relative to wall portion (368) that is connected to the plate (see FIGS. 15, 21A, and 21B). The upper wall portion (384) may be characterized as a collar (see FIGS. 15, 21A, and 21B). The vessels (376) have a substantially cup-shaped bottom and thin wall portions (368) that tapers to form a cone shape (see FIGS. 15, 21A, and 21B). Examiner has interpreted "and/or, in a wall portion (11) adjoining it, are a wall thickness which gradually increases upwardly" as the wall portion with a wall thickness which increases upwardly adjoins the thin, tapering wall portion. In this case

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the vessels (376) have a wall portion (368) of a wall thickness gradually increasing upwardly adjoining the thin wall portion (384) (see FIGS. 15, 21A, and 21B).

Referring to claims 35 and 37, Examiner has interpreted molding points as points that are molded. Examiner has interpreted edge-sided molding points as points at the edges and sides that are molded. Atwood et al. disclose that the entire microtitration plate may be molded, including the vessel bottoms and frame and its sides and edges. Inherently, the vessel bottoms and the sides and edges of the frames have infinite molding points.

Therefore, Atwood et al. include all the limitations in claims 1-3, 31-37, 40, and 41.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,340,589 to Turner et al. or U.S. Patent No. 5,475,610 to Atwood et al. in view of U.S. Patent No. 5,516,491 to Kath et al. and/or U.S. Patent No. 4,072,243 to Conant et al. and/or U.S. Patent No. 4,746,490 to Saneii and/or U.S. Patent No. 4,564,359 to Ruhland.

Referring to claims 41 and 42, neither Turner et al. nor Atwood et al. disclose vessel made of liquid silicone rubber (LSR). However, it is very well known to coat a vessel with liquid silicone rubber for a host reasons. Kath et al. disclose that dipping polypropylene vessels in silicone rubber provides a better septum seal since upon piercing the polypropylene partially reseals the hole (see COL. 3, lines 1-8). Conant et al. disclose that coating brittle non-metallic engineering materials, including items for the laboratory, with certain films such as silicone yields products with good impact strength, shock resistance, good heat distribution, good pressure capability, and extremely high safety factor (see ABSTRACT; COLS. 8 and 9; CO. 10, lines 1-10). Saneii discloses that reaction vessels are preferably silicone coated to prevent resin particles, which carry the chemical or biological material of interest, from adhering to the reaction vessel walls (see

COL.11, lines 50-54). Ruhland discloses that silicon rubber is a blood friendly compatible material, which is very good when DNA sample for PCR is obtained from a blood samples (see COL. 5, lines 11-14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the vessel of Turner et al. or Atwood et al. to made it out of liquid silicone rubber for a better septum seal as in Kath et al. and/or stronger container with good heat distribution as in Conant et al., preventing resin particles from adhering to reaction vessel walls as in Saneii, and/or accommodating blood samples.

21. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,475,610 to Atwood et al. in view of U.S. Patent No. 6,063,282 to Moulton and/or U.S. Patent No. 6,027,695 to Oldenburg et al. and/or U.S. Patent No. 6,040,171 to Ho et al.

Referring to claims 38 and 39, Atwood et al. do not disclose the frame made of an amorphous plastic, such as polycarbonate. Moulton discloses a frame (12) made of polycarbonate, which is resistant to organic solvents and enable a human user to view the contents or processes occurring from within (see COL. 2, lines 61-67; COL. 3, lines 1-3). Oldenburg et al. disclose making the microtiter plate from a high reflective material such as polycarbonate to enhance the performance of the plate when used for luminescence measurements (see COL. 8, lines 30-35). Ho et al. disclose that the microplate is preferably formed from a material, such as polycarbonate for its optical transmission properties (see COL. 3, lines 32-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the microtitration plate of Atwood et al. to make the frame from polycarbonate for a frame

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resistant to organic solvents and enabling a human user to view within the frame as in Moulton and/or performance enhancement of the microtiter plate when conducting luminescence measurements as in Oldenburg et al. and/or particular optical transmission properties as in Ho et al.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. They include one or more limitations in the claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743

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June 16, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700

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